UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte YOSHIO HIRAKI, SATOSHI YOSHIKAWA, TAKASHI KINOSHITA, TATSUTOSHI SHIRAISHI and TOSHIRO SONE

Appeal No. 2005-1168
Application No. 09/913,721

HEARD August 23, 2005

Before WILLIAM F. SMITH, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a composition containing vitamin A and a fatty acid monoglyceride. The examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 134. Because we construe the claims to encompass compositions that would have been obvious to those skilled in the art, we affirm.

Background

The specification discloses a known preparation containing a "lamellar structure comprising a fatty acid monoglyceride as a main component." Page 2. This preparation "has a high moisturizing effect," but tends to foam during production, "which becomes a problem from the viewpoint of production efficiency." Id. The specification also

discloses that vitamin A has been used to reduce skin damage due to aging and exposure to sunlight. Id. "However, vitamin A is insufficient in effects of improving skin roughness and suppressing wrinkling and also involves a problem that it forms the cause of offensive smell and stickiness." Id.

The specification discloses "a skin preparation for external use which has high effects of improving skin roughness and suppressing wrinkling, etc., shows neither any offensive smell nor stickiness, and exhibits controlled foaming upon production." Pages 2-3.

> "[W]hen an oil phase mixture containing a fatty acid monoglyceride and vitamin A is prepared and a lamellar structure is then prepared from the oil phase mixture, higher effects of improving skin roughness and suppressing wrinkling are achieved, and the smell of vitamin A, foaming upon the production of the lamellar structure can be suppressed, and moreover shelf stability of the resulting external skin care composition is also improved.

Page 3.

The specification states that "[t]he lamellar structure used in the present invention contains the fatty acid monoglyceride as a main component. As constitutive components of the lamellar structure, other components may be used in addition to the fatty acid monoglyceride. Such constitutive components include cholesterol and the like. The incorporation of cholesterol is particularly preferred for the purpose of improving the stability of the lamellar structure." Page 4.

The preparation can contain vitamin A itself or a vitamin A derivative. "[A]ny of retinol, retinal of the aldehyde type, retinoic acid of the carboxylic acid type, and esters such as retinol acetate and retinol palmitate may be preferably used." Page 6.

Discussion

1. Claim construction

Claims 1-9 and 11-13 stand or fall together. See the Appeal Brief, page 3. Claim 1 is representative of this group and reads as follows:

> 1. A skin preparation comprising a lamellar structure consisting essentially of one or more fatty acid monoglyceride(s), and one or more of vitamin A and vitamin A precursor(s), derivative(s) and decomposed product(s) thereof.

Claim 10 was separately rejected and stands or falls alone. Claim 10 reads as follows:

> 10. The skin preparation according to Claim 1, wherein said lamellar structure is a multi-lamellar vesicle.

Thus, claim 1 is directed to a skin preparation comprising vitamin A (or a derivative thereof) and "a lamellar structure consisting essentially of one or more fatty acid monoglyceride(s)." Claim 10 adds the limitation that the lamellar structure is a multi-lamellar vesicle.

The central issue in this appeal is whether claim 1's "consisting essentially of" transition phrase limits the lamellar structure to one that contains no lipids other than fatty acid monoglycerides. "'Consisting essentially of' is a transition phrase commonly used to signal a partially open claim in a patent. . . . By using the term 'consisting essentially of,' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention." PPG Indus. Inc. v. Guardian Indus. Corp, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998).

In this case, the "consisting essentially of" transition applies to the components of the lamellar structure, not the claimed composition as a whole. That is, the lamellar structure consists essentially of fatty acid monoglyceride(s), and the claimed composition comprises the lamellar structure and vitamin A (or a derivative). The question therefore arises, what are the basic and novel properties of the lamellar structure?

Appellants argue that "[t]he basic and novel characteristics of the invention are set forth on page 4, line 11 through page 5, line 2, which clearly sets forth the fact that a lamellar structure may be formed using only a fatty acid monoglyceride without the addition of a secondary lipid . . . and with an optional sterol additive, i.e., cholesterol, which is added only for the purpose of improving the stability of the lamellar structure." Appeal Brief, page 4.

Thus, according to Appellants, the basic and novel characteristic of the lamellar structure is that it contains no lipids other than monoglycerides. We disagree. The specification does not state that being made up only of fatty acid monoglycerides is the basic and novel characteristic of the lamellar structure. A patent applicant is "entitled to provide its own definition for the terms used in its patent claim, including the transition phrase 'consisting essentially of.' . . . Thus, [an applicant can define] . . . the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention." PPG Indus., 156 F.3d at 1355, 48 USPQ2d at 1355.

Appellants' specification does not make clear what they regard as a material change in the basic and novel characteristics of the lamellar structure. However, it does

say that a preparation containing vitamin A without a lamellar structure is not very effective in improving skin roughness, smells bad, and is sticky. Page 2. The claimed composition, by contrast, is more effective in improving skin roughness, does not smell, and "gives users a dry feel upon use" (i.e., no stickiness). Page 3. Since the only disclosed difference between the prior art vitamin A-containing composition and the disclosed composition is the presence of a lamellar structure, the improved properties of the overall composition seem to be attributable to the lamellar structure.

Thus, we conclude that the basic and novel characteristics of the lamellar structure in the claimed composition is that it improves the skin-softening property, smell, stickiness, and stability of the composition when combined with vitamin A, as compared to a vitamin A-containing composition that lacks a lamellar structure.

2. Obviousness

The examiner rejected claims 1-9 and 11-13 under 35 U.S.C. § 103 on the basis that the claimed preparation would have been obvious in view of Mathur.[1] Mathur teaches a method of "forming lipid vesicles using cosmetic, pharmaceutical, or dermatologically useful substances as the primary vesicle formers." Col. 1, lines 65-68. The examiner found that Mathur teaches lipid vesicles made of a blend of amphiphilic lipids and that "glyceryl monostearate is among the most preferred lipids used. See col. 3, lines 41-51." Examiner's Answer, page 3. The examiner also found that Mathur's Examples 2 and 5 show retinoic acid formulations in which the retinoic acid is encapsulated in the vesicles. Id. The examiner reasoned that a person of ordinary skill in the art would have found it obvious to modify the exemplified formulations by

[1] Mathur et al., U.S. Patent 5,260,065, issued Nov. 9, 1993.

substituting glyceryl monostearate for, e.g., the glyceryl distearate in Example 5 because Mathur teaches that both glyceryl monostearate and glyceryl distearate are preferred primary lipids and therefore the skilled artisan would have expected the modified composition to have properties similar to the exemplified compositions. Id., page 4.

Appellants argue that Mathur's compositions invariably include a secondary lipid and that this "secondary lipid is excluded from the claims by the recitation of a term 'consisting essentially of', since the addition of a secondary lipid would change the essential nature of the composition of the present claims." Appeal Brief, page 4. "[I]t is clear that the term 'consisting essentially of' excludes secondary lipids, which would change the essential nature of the composition, but not a sterol additive, i.e., cholesterol, which is only useful in improving the stability of a lamellar structure and not necessary for the formation of a lamellar structure." Id.

We do not agree with Appellants' claim interpretation. As we have construed claim 1, it encompasses lamellar structures that contain fatty acid monoglyceride(s) and anything else that does not affect the skin-softening, odor, or stability properties of the claimed composition. There is no evidence in the record that adding a lipid other than a fatty acid monoglyceride to the lamellar structure would make the claimed composition less skin-softening, more smelly, or less stable on storage. Our interpretation, in fact, is consistent with the specification's disclosure that "other components may be used [in the lamellar structure] in addition to the fatty acid monoglycerides." Page 4. Based on the evidence of record, we conclude that the claims read on the composition made obvious by Mathur's disclosure.

The examiner also rejected claim 10 as obvious in view of the combined disclosures of Mathur and Yiournas.[2] The examiner noted that "Mathur is directed to paucilamellar vesicles, [and] the reference does not teach multilamellar structures." Examiner's Answer, page 4. The examiner cited Yiournas to make up for this difference.

Yiournas teaches that "multilamellar vesicles ('MLV's') . . . are onion-like structures having a series of substantially spherical shells formed of lipid bilayers interspersed with aqueous layers." Col. 1, lines 32-37. Another "type of lipid vesicle, which is particularly well suited for transport of either lipids or aqueous materials, is the paucilamellar vesicle ('PLV')." Col. 1, lines 42-44. "Each type of lipid vesicle has distinct advantages for certain uses. Because of the relatively large amount of lipid in the lipid bilayers of the MLV's, they are considered best for encapsulation or transportation of lipophilic materials. . . . PLV's can transport large quantities of aqueous or lipophilic materials." Col. 1, lines 53-67. Yiournas teaches "a method of producing multilamellar or paucilamellar lipid vesicles and an apparatus useful in their production." Col. 2, lines 66-68.

The examiner concluded that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the paucilamellar vesicle formulations in Mathur by formulating multilamellar vesicles as motivated by Yiournas because of the expectation of successfully producing lipid vesicles that can similarly encapsulate and transport large amounts of lipophilic materials." Examiner's Answer, page 5.

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[2] Yiournas et al., U.S. Patent 5,013,497, issued May 7, 1991.

We agree with the examiner's reasoning and conclusion: Mathur teaches that retinoic acid is a "water insoluble material", col. 5, lines 23-24, and Yiournas teaches that multilamellar vesicles are the preferred vesicles for lipophilic materials. Those skilled in the art would have known that "water insoluble", "hydrophobic", and "lipophilic" all mean the same thing, and therefore would have found it obvious to combine Yiournas' method of making multilamellar vesicles with the vitamin A- and glyceryl monostearate-containing composition made obvious by Mathur.

Appellants argue that Yiournas "does not teach or suggest a skin preparation having a lamellar structure consisting essentially of one or more fatty acid monoglyceride(s), and one or more of vitamin A and vitamin A precursor(s), derivative(s) and decomposed product(s), as in the present claims. Claim 10 distinguishes over the combination of references." Appeal Brief, page 5.

We disagree. For the reasons discussed above, we agree with the examiner that the cited references would have suggested the preparation of claim 10 to a person of ordinary skill in the art.

Summary

The evidence of record does not show that the presence of a second lipid in the lamellar structure of the claimed composition would change its basic and novel properties. The instant claims therefore read on the compositions made obvious by the prior art. The rejections under 35 U.S.C. § 103 are affirmed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136 (a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Donald E. Adams
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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